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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,510	09/17/2005	Martin Gimmestad	BAFM0001-100	4461

34132 7590 11/24/2006

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EXAMINER	
MEAH, MOHAMMAD Y	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,510	GIMMESTAD ET AL.	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/18/06.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 16-26 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/20/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending in the instant application for examination. With preliminary amendment 09/18/06 applicant elected without traverse group I (claims 1-15) for examination.

Election/Restriction

During the preliminary amendment of this application, the applicant, on date 9/18/2006 elected without traverse Group I (claims 1-15), drawn to bacterial culture of mutant strain of *P. fluorescens*, for examination. Groups II-IV (claims 16-26) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to as non elected groups.

Priority

Acknowledgement is made of applicant's priority date based on PCT application filing date of 7/24/2003 for PCT/ NO 03/00257 and filing date 7/26/02 for application foreign application Norway 20023581.

Claim Objections

Claims 6, 9 and 11 is objected in recitation of "claims 1". Appropriate correction is required.

Claim Rejections

35 U.S.C 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 24 rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 12 is confusing in recitation " --selected from the group –", as the group has only one member.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 8-9, 11, 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of mutant strain of *P. flurescens* having alginate production activity wherein one or more alginate biosynthetic pathway genes (such as C-5 epimerase, algG-gene, etc are mutated by any

means . The mutant strain of *P. flurescens* claimed in the instant claims, produced by mutating one or more alginate biosynthetic pathway genes (such as C-5 epimerase, algG-gene, etc) by any means ,is a large variable genus containing many mutant strains from many sources. The specification teaches few mutant strains of *P. flurescens* (pF201, pf2012,etc recited in claim 5), which do not represent all mutant strains recited in the instant claims. Specification neither teaches the structures of all C-5 epimerase, algG-gene and other alginate biosynthetic pathway genes nor teaches how all *P. flurescens* strain will be modified. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-4, 6, 8-9, 11, 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the few mutant strain of *P. flurescens* (pF201, pf2012,etc recited in claim 5) does not reasonably provide enablement for any mutant strain of *P. flurescens*, produced by mutating one or more alginate biosynthetic pathway genes (such as C-5 epimerase, algG-gene, etc) by any means. The claims broadly recite any mutant strain of *P. flurescens* produced any means. There are many means of making mutant strain such as mutations of the gene itself, addition of inhibitors,

modification of endogenous modulators, mutating, deleting of specific amino acid residues etc., The specification fails to describe how any *P. flurescens* strain expressing from any source can be mutated by any means to produce alginate.

Claims 1-4, 6, 8-9, 11, 13-14 are so broad as to include many mutant strains of *P. flurescens*, produced by mutating one or more alginate biosynthetic pathway genes (such as C-5 epimerase, algG-gene, etc) by any means. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number way of mutating one or more alginate biosynthetic pathway genes to provide mutant strains of *P. flurescens*,. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a few biosynthetic pathway genes such as C-5 epimerase, algG-gene.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence

where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, there are many means of controlling gene function such as mutations of the gene itself, addition of inhibitors, modification of endogenous modulators, mutating individual nucleic acid, etc. It is not routine in the art to control a gene by any means to obtain desired outcome. Without knowing the structural feature of the protein it encodes, controlling the gene by any means (i.e., such as modification of the gene by mutations) to obtain desired function is unpredictable. Biosynthesis of alignate involve with a large enzymes. Controlling one gene without affecting other genes that involve in the alignate synthesis is difficult. The specification does not support the broad scope of the claims which encompass mutant strains of *P. flurescens*, produced by mutating one or more alginate biosynthetic pathway genes (such as C-5 epimerase, algG-gene, etc) by any means because the specification does **not** establish: (A) regions of the DNA structure of algG gene which should be modified to control alignate synthesis activity and/or how to control by any means the algG gene or any gene involved in alignate synthesis to obtain desired function without effecting other genes that involve in the alignate synthesis ; (B) the general tolerance of algG gene or other alignate bio-synthetic genes to modification and extent of such tolerance towards controlling the gene with any means; (C) a rational and

predictable scheme for modifying any algG residues or residues of other genes with an expectation of obtaining the desired biological function; and / or controlling the gene by any means towards such biological function (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any mutant strains of *P. flurescens*, produced by mutating one or more alginate biosynthetic pathway genes by any means. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making mutant strains of *P. flurescens*, by mutating one or more alginate biosynthetic pathway genes by any means is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5,7, 10, 12, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims recite novel mutant strains having various plasmid containing novel sequences. Since the mutant organism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed organisms are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. ɔ 112 may be satisfied by a deposit of the mutant organism. The specification does not disclose a repeatable process to obtain the mutant organisms and it is not apparent if they are readily available to the public. Accordingly, it is deemed that a deposit of mutant organism should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or

condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;

2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Huisman et al. (US 2004/0014197).

Huisman et al. teach mutant strain of *P. fluorescens* producing various polyhydroxy compounds including alginates (upto 80 g/L) wherein *P. fluorescens* strain further is integrated with nuclease gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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